



CMS-1439-RCN

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Chapter IV**

**Office of Inspector General**

**42 CFR Chapter V**

**[CMS-1439-RCN]**

**RIN 0938-AR30**

**Medicare Program; Final Waivers in Connection With the Shared Savings**

**Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG), HHS.

**ACTION:** Interim final rule; continuation of effectiveness and extension of timeline for publication of final rule.

**SUMMARY:** This document announces the continuation of effectiveness of an interim final rule and the extension of the timeline for publication of the final rule. This document is issued in accordance with section 1871(a)(3)(C) of the Social Security Act (the Act), which allows an interim final rule to remain in effect after the expiration of the timeline specified in section 1871(a)(3)(B) of the Act if the Secretary publishes a notice of continuation prior to the expiration of the timeline.

**DATES:** This document is effective on **[insert the date of publication in the Federal Register]**.

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### **FOR FURTHER INFORMATION CONTACT:**

Catherine Bernstein (410) 786-6887 or Lisa Ohrin (410) 786-8852, for general issues and issues related to the Physician Self-Referral Law.

Patrice Drew (202) 619-1368, for general issues and issues related to the Federal anti-kickback statute or civil monetary penalties law.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

Section 1871(a)(3)(A) of the Social Security Act (the Act) sets forth certain procedures for promulgating regulations necessary to carry out the administration of the insurance programs under Title XVIII of the Act. Section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of a final rule based on the previous publication of a proposed rule or an interim final rule. In accordance with section 1871(a)(3)(B) of the Act, such regular timeline may vary among different final rules, based on the complexity of the rule, the number and scope of the comments received, and other relevant factors. The timeline for publishing the final rule, however, cannot exceed 3 years from the date of publication of the proposed or interim final rule, unless there are exceptional circumstances. After consultation with the Director of OMB, the Department, through CMS, published a notice in the December 30, 2004 **Federal Register** (69 FR 78442) establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

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Section 1871(a)(3)(C) of the Act states that a Medicare interim final rule shall not continue in effect if the final rule is not published before the expiration of the regular timeline, unless the Secretary publishes at the end of the regular timeline a notice of continuation that includes an explanation of why the regular timeline was not met. Upon publication of such a notice, the timeline for publishing the final rule is extended for 1 year.

### **II. Notice of Continuation**

Section 1899 of the Act establishes the Shared Savings Program to encourage the development of Accountable Care Organizations (ACOs) in Medicare. The Shared Savings Program is one of the first initiatives implemented under the Affordable Care Act aimed specifically at improving value in the Medicare program—that is, both higher quality and lower total expenditures for individual Medicare beneficiaries and the Medicare program. The Shared Savings Program final rule appeared in the November 2, 2011 **Federal Register** (76 FR 67801), and the first performance year concluded on December 31, 2013.

In connection with the Shared Savings Program, section 1899(f) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws. Specifically, section 1899(f) of the Act provides that "[t]he Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of [the] Act as may be necessary to carry out the provisions of [section 1899 of the Act]." The Secretary determined that certain waivers were "necessary," consistent with this statutory standard, and, CMS and OIG jointly published an interim final rule with comment period (hereinafter referred as

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"Waiver IFC") (76 FR 67992; November 2, 2011) in conjunction with the issuance of the Shared Savings Program final rule.<sup>1</sup> The Waiver IFC established waivers of the application of the Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), and certain civil monetary penalties (CMP) law provisions (sections 1128A(a)(5), (b)(1), and (b)(2) of the Act) to specified arrangements involving ACOs participating in the Shared Savings Program.

Because the Waiver IFC was issued under the authority at section 1899(f) of the Act, it is considered a Medicare rule subject to the conditions of section 1871(a)(3)(C) of the Act. This document extends the timeline for publication of a final rule concerning Shared Savings Program waivers promulgated in the Waiver IFC. In the absence of this continuation notice, the Waiver IFC would expire, creating legal uncertainty for ACOs participating in the Shared Savings Program and potentially disrupting ongoing business plans or operations of some ACOs.

Our goal is to ensure that the regulations setting forth waivers of the fraud and abuse laws continue to be closely aligned with the Shared Savings Program regulations.

Based on stakeholder feedback and CMS's experience operating the Shared Savings Program, CMS determined that certain modifications to the Shared Savings Program regulations were necessary. Therefore, CMS is currently developing a proposed rule regarding the Shared Savings Program. In light of the planned issuance of a proposed rule and the importance of final waiver regulations that align with the Shared Savings Program, we believe the prudent course of action at this time is to extend the

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<sup>1</sup> The Waiver IFC was issued as part of a cross-agency, coordinated effort by several Federal agencies to issue

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effectiveness of the Waiver IFC. In addition, we believe that an extension of the Waiver IFC will avoid impediments to the development of innovative care models envisioned by the Shared Savings Program and new approaches to the delivery of health care for beneficiaries (see 76 FR 68008). As noted previously, the Secretary has determined that the waivers are necessary to carry out the Shared Savings Program.

Our decision to extend the Waiver IFC, rather than issue a final rule at this time, should not be viewed as a diminution of the Department's commitment to establish waivers "to foster the success of the Shared Savings Program, the purposes of which are to promote accountability for a Medicare patient population, manage and coordinate care for Medicare fee-for-service beneficiaries, and encourage redesigned care processes to improve quality" (76 FR 68008). Our goal remains "to balance effectively the need for ACO certainty, innovation, and flexibility in the Shared Savings Program with protections for beneficiaries and the Medicare program" (76 FR 68008). At this time, we believe we can best achieve this balance by issuing this continuation notice.

We also believe that we would benefit from additional input from stakeholders to inform our understanding of --(1) how and to what extent ACOs are using the waivers; (2) whether the existing waivers serve the needs of ACOs and the Medicare program; (3) whether the waivers adequately protect the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services; and (4) whether there are new or changed considerations that should inform the development of additional notice and comment rulemaking.

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This document extends the timeline for publication of a final rule through November 2, 2015. In accordance with section 1871(a)(3)(C) of the Act, the Waiver IFC shall remain in effect through November 2, 2015, unless a final waiver rule becomes effective on an earlier date.

This document was approved by the Administrator for the Centers for Medicare and Medicaid Services and the Inspector General for the Department of the Health and Human Services as it relates to the authorities that fall within the respective purviews of their offices. This includes, without limitation, section 1877(a) of the Act for the Administrator and sections 1128A(a)(5), (b)(1), and (b)(2) and 1128B(b)(1) and (b)(2) of the Act for the Inspector General.

**Authority:** Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare--Hospital Insurance Program; and No. 93.774, Medicare--Supplementary Medical Insurance Program)

**Dated:** October 10, 2014

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**C'Reda Weeden,**

Executive Secretary to the  
Department,  
Department of Health and Human  
Services.

**BILLING CODE 4120-01-P**

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**[FR Doc. 2014-24663 Filed 10/16/2014 at 8:45 am; Publication Date: 10/17/2014]**